

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

X 16638

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

8 Feb 2006

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION

See paragraph 2 below

International application No
PCT/US2005/010148

International filing date (day/month/year)
29.03.2005

Priority date (day/month/year)
08.04.2004

International Patent Classification (IPC) or both national classification and IPC
A61M5/315

Applicant

ELI LILLY AND COMPANY

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. **type of material:**
 a sequence listing
 table(s) related to the sequence listing
 - b. **format of material:**
 in written format
 in computer readable form
 - c. **time of filing/furnishing:**
 contained in the international application as filed.
 filed together with the international application in computer readable form.
 furnished subsequently to this Authority for the purposes of search.
3. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or
industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-8
Inventive step (IS)	Yes: Claims	
	No: Claims	1-8
Industrial applicability (IA)	Yes: Claims	1-8
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: US-A-2 941 530
D2: US 2003/233075
D3: US-A-5 620 425
D4: US-A-2 551 414
D5: FR-A-2 547 201

Novelty Article 33(2) PCT

2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claims 1-8** does not appear to be new in the sense of Article 33(2) PCT.
 - 2.1. The document D1 is regarded as being the closest prior art and discloses (the references in parentheses applying to this document) a piston for a pharmaceutical cartridge comprising (figures 1-6):

claims 1,3-5: - a body (31+34) having a distal end (31), a proximal end (the opposite of 31) and a sealing periphery (34), said distal end (31) in contact with a medication disposed within the cartridge barrel (11), said sealing periphery (34) in sealing contact with an interior surface of the barrel, said distal end and sealing periphery unitarily constructed from a material having a first hardness (resilient plastic);
- a cylindrical core (39) within said body and sealed within the cartridge barrel between the distal end and the proximal end (sealed by the plug 36), said core constructed from at least one material having a second hardness greater than said first hardness (metal or hard and non-flexible material)

claim 2: - said core (39) is completely encapsulated within said body

claims 6-8: - said core axially extends between about 25% to 75% of an axial length of said body or about 50% to 75% of the axial length of said body.

2.2. In addition the technical features from claims 1-2 and 4-8 are disclosed by the documents D2-D5.

Document D2: - Figures 1-10, elastic body (10), plug (4), hard core (2, inflexible material)

Document D3: - Figure 1, column 5 lines 1-14, elastic cover and a hard core

Document D4: - Figures 1-8, piston (12) is made of an elastic material and contains a hard insert (14)

Document D5: - Figures 1-2, piston (enveloppe souple 7,2+3+4), and hard core (noyau indéformable 5)

Re Item VII

Certain defects in the international application

1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the **relevant background** art disclosed in the documents D1-D5 is not mentioned in the description, nor are these documents identified therein.
2. Independent claim 1 is not in the **two-part form** in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
3. The features of the claims are not provided with **reference signs** placed in parentheses (Rule 6.2(b) PCT).
4. The vague and imprecise statement (spirit) in the description on page 6 last line implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity of the claims (Article 6 PCT) when used to interpret them.